UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,136	01/12/2001	Stephen Nuss	990356.ORI	2264

23595 7590 05/05/2005

NIKOLAI & MERSEREAU, P.A.
900 SECOND AVENUE SOUTH
SUITE 820
MINNEAPOLIS, MN 55402

EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,136	NUSS, STEPHEN	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,16-20 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,16-20 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 12 is objected to because of the following informalities: line 1 states "adopted". Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 12, 16 – 20 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,776,330 to Chapman et al. in view of U.S. Patent No. 6,132,389 to Cornish et al.

In regards to claims 12, 16 – 20 and 24 – 27, Chapman et al. discloses a guidewire capable of insertion into a vascular system of a patient during the course of a catheterization procedure having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (Col. 4, lines 16 – 23; Col. 11, line 67 – Col. 12, line 2; Col. 13, lines 61 – 63), but fails to disclose the guidewire having a tapered distal end portion, a helical coil attached to the distal end, a rounded distal tip member on the distal end, a polymeric or a hydrophilic coating, or a diameter in the range of 0.005 inch and 0.040 inch. However, Cornish et al. discloses a guidewire having a tapered distal end portion (18), a helical coil (20) attached to the distal end, a rounded distal tip member (58) on the distal end, a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60), and a diameter in the range of 0.005 inch and 0.040 inch (Col. 4, lines 19 – 28). It would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a tapered distal end portion as taught by Cornish et al. in order to increase the flexibility of the distal end of the guidewire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a helical coil attached to the distal end as taught by Cornish et al. in order to facilitate fluoroscopic viewing of the device while in use and to increase the diameter of the distal section without adding substantial stiffness to the section (Col. 4, lines 36 – 45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a rounded distal tip member on the distal end as taught by Cornish et al. in order to attach the helical coil to the guidewire and o further smooth the transition from the guidewire to the helical coil (Col. 5, lines 5 – 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by Chapman et al. to include a polymeric or a hydrophilic coating as taught by Cornish et al. in order to increase the lubricity of the guidewire (Col. 3, lines 50 – 60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the guidewire as disclosed by Chapman et al. to be in the range of 0.005 inch and 0.040 inch as taught by Cornish et al. or to be any diameter as since applicant has not disclosed that using a diameter in the range of 0.005 inch and 0.040 inch provides any advantage, or solves a stated problem, or is used for any particular purpose. Furthermore, a change in the size of a prior art device is a design consideration within the skill of the art. ***In re Rose***, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

4. Claims 12, 16 – 20 and 24 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent No. 4,776,330 to Chapman et al.

In regards to claims 12, 16 – 20 and 24 – 27, Cornish et al. discloses an intravascular guidewire adapted for insertion into the vascular system of a patient during the course of a catheterization procedure (Col. 1, lines 20 – 67) having a tapered distal end portion (18), a helical coil (20) attached to the distal end, a rounded distal tip member (58) on the distal end, a polymer coating and a hydrophilic coating (Col. 3, lines 50 – 60), and a diameter in the range of 0.005 inch and 0.040 inch (Col. 4, lines 19 – 28). Cornish et al. discloses the wire being formed of a titanium alloy but fails to disclose the titanium alloy being a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. Chapman et al. discloses a guidewire capable of insertion into a vascular system of a patient during the course of a catheterization procedure having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (Col. 4, lines 16 – 23; Col. 11, line 67 – Col. 12, line 2; Col. 13, lines 61 – 63), It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the titanium alloy as disclosed by Cornish et al. to include a titanium molybdenum alloy having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight as taught by Chapman et al. in order to provide a resilient, physiologically inert guidewire (Col. 4, lines 16 – 23).

Response to Arguments

5. Applicant's arguments filed 12/20/04 have been fully considered but they are not persuasive. Applicant has asserted that Chapman et al. does not disclose a guidewire having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight. However,

the Examiner disagrees. Applicant acknowledges that Chapman et al. states that the components of the kit of the invention are made from a physiologically-inert titanium-based alloy, i.e. 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (Col. 4, lines 16 – 19). Chapman et al. further states that all of the implants shown in the various embodiments are made of a resilient, physiologically-inert titanium-based alloy (Col. 11, line 67 – Col. 12, line 2). At Col. 13, lines 60 – 63, Chapman et al. states that the guidewire could be left in place as part of the implanted elongated implant. Therefore, since the guidewire is disclosed a part of the implant, the guidewire is disclosed as being formed of the claimed alloy.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700